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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,632	11/20/2000	Wanda A. Cromlish	43639.010400	3503

7590 07/15/2005

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EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/731,632

Applicant(s)

CROMLISH ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-15,19 and 22-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-7,11-15,19 and 22-27 is/are allowed.
- 6) ☒ Claim(s) 9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6-13-05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Reissue Application***

Claims 1-7, 9-15, 19, 22-27 are currently pending in this re-issue application.

Applicants' amendments and arguments filed on 6-13-05, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,543,297 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

### ***Oath/Declaration***

The reissue oath/declaration filed with the amendment filed on 6-13-05 has been considered.

### ***Sequence Compliance***

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is

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particularly noted that applicants do not provide specific SEQ ID NO to the sequences depicted in the drawings either on the drawings or in the figure description. Please see particularly 37 CFR 1.821(d) and (e).

In response to the previous Office action, applicant has not responded to the above sequence compliance requirement.

Applicant's request for transfer of electronic form of sequence information from the parent application to the instant application has been received and said transfer has been made.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 9-10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rodan et al. (J. Bone Mineral Res. 1986, Vol. 1(2):213-220 cited in Form 1449). Claim 9-10 in this instant application is drawn to a composition comprising an osteosarcoma cell preparation having  $8 \times 10^4$  to  $2 \times 10^6$  cells per c.c. or 100-400 microgram of osteosarcoma microsomes and 10 to 20 micro liters of arachidonic acid per c.c. of cell preparation.

Rodan et al. teach several types of human osteosarcoma cell and provide cell culture composition of the same. The reference also teaches the use of said cells for assay of COX activity along with exogenous use of arachidonic acid in such reactions. Rodan et al. actually investigate the basis for differences in prostaglandin synthesis among osteosarcoma cell lines and

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examine the effect of a number of bone resorbing agents on prostaglandin production and report that the differences in PGE synthesis between osteoblastic and non-osteoblastic rat osteosarcoma cells were associated with COX dependent release of arachidonic acid.

With the above teaching of Rodan et al. in hand, it would have been obvious to those skilled in the art to make several types of cell preparations to study the above aspects, one of which would be a cell preparation between  $10^3$  or  $10^5$  or  $10^9$  or  $8 \times 10^4$  to  $2 \times 10^6$  osteosarcoma cells per c.c. or 100-400 microgram of osteosarcoma microsomes per c.c. of cell preparation (as required) along with varying amounts of arachidonic acid such as 10 to 20 or 100 micro liters. One of ordinary skill in the art would have been motivated to do so in order to set up reactions to study the effects of bone resorbing agents on PGE synthesis. One of ordinary skill in the art would have a reasonable expectation of success since Rodan et al. provide the cells and a detailed information regarding their role and their physiology.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

In response to the previous Office action, applicant has traversed the above rejection arguing that even if it is assumed, for the sake of argument, that the reference teaches the osteosarcoma cell line, the protocol characterized by the Examiner would result in the expression and measurement of both COX-1 and COX-2 and therefore a compound that selectively inhibits only COX-2 cannot be obtained and that claims 9 and 10 are specifically directed to osteosarcoma cells which selectively express COX-2. Applicant also directs the Examiner to the reference of Wong et al. Examiner respectfully disagrees with such a line of argument. This is because, claims in question are not drawn to the limitation of any protocol for assaying specifically COX-2 using the claimed cells. Therefore, arguing that the protocol characterized by the Examiner would result in the expression and measurement of both COX-1 and COX-2 is highly misplaced. Furthermore, while the specification teaches that the U-937 cell line selectively expresses COX-1 but not COX-2 (in page 3) there is no such teaching of selective expression of COX-2 in the claimed osteosarcoma cell. While the reference of Wong et al. may teach the selective expression of COX-2 in the claimed cells, said reference has not been incorporated into the specification. Therefore, Examiner continues to maintain that claims 9-10 would have been *prima facie* obvious to those skilled in the art.

### ***Conclusion***

Claims 1-7, 11-15, 19, 22-27 are allowable.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-1600 for regular communications and for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Manjunath N. Rao". The signature is stylized with a large initial "M" and a long horizontal stroke.

Manjunath N. Rao  
Primary Examiner  
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July 5, 2005